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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,270	03/12/2004	Michael P. Wallace	30-7038142001 04-049 (US0	7229

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EXAMINER	
PATEL, JOY	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,270	WALLACE ET AL.	
	Examiner	Art Unit	
	Joy P. Patel	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 8-43* is/are rejected.

7)☒ Claim(s) *7* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 March 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~3/2004~~ 3/25/04 & 9/13/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to because item 122 (the skeletal spring member) is not labeled in figure 9, but is described in the specifications (page 14, line 16). Element 154, "the adapter of the extension (106)", which is mentioned on page 22, line10 is not present in any of the provided figures. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed

of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because the abstract exceeds the allowable word limit. Correction is required. See MPEP § 608.01(b).
3. The disclosure is objected to because of the following informalities: On page 1, line 6, the serial number for the copending US Patent Application is not provided. If it is available, it should be inserted here. On page 9, line 21, "secondary stimulation leads" is defined as element 104, however, 104 is the stimulation source. On page 14, line 21, "lateral spring segments" are defined as element 144, however, element 144 is the "main spring segment". It is suggested that "lateral spring elements" be changed to element 145. On Page 14, line 23, element number 146 should be

changed to 136, since the description is referring to figure 9. On page 15, line 6, the second appearance of element 152 should be removed, since the sentence reads ".....element 152, which is similar to the previously described spring element 152...". On page 16, line 4, elements 175 and 166 are described to be present in figure 11. However, these elements are present in figure 12. It is suggested that "figure 11" be changed to "figure 12" in this line. On page 19, line 17, the stimulation sources are defined as element 106. However, the stimulation source is previously defined as element 104. On page 19, line 24, the stimulation source is once again mentioned as being element 106. However, the stimulation source has previously been defined as element 104. On page 20, line 8, the proximal end is defined as element 113. However, on the previous line, the proximal end is defined as element 11. On page 20, line 9, the distal end is defined as element 111. However, on page 20, line 7, the distal end is defined as element 113. On page 22, line 12, the "connector of the lead extension" is defined as element 156. However, element 156 has previously been defined as the paddle of figure 11.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 5, 8-20, 22-24, 26-34, 36-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuzma et al. (US 6,205,361).
5. In regard to claim 1, Kuzma discloses, "...the electrode array, 10 (Figure 1), is made in the form of a silicone paddle having a number of electrode contacts..." (Column 3, lines 30-31). Kuzma further discloses that the "electrode contacts are typically wound around a shape-memory element, 12..." (Column 3, lines 42-43). Kuzma also adds: "The memory element, 12, is flexible or resilient, so that it can be folded or bent to another shape as desired or needed, but in the absence of an external folding or bending force, assumes the open, paddle shape shown in Figure 1" (Column 3, lines 50-54). This indicates that the spring layer (12) has a higher stiffness than the insulative membrane (silicone).
6. In regard to claims 2, 17, 33, Kuzma discloses, "Each row of spaced-apart electrodes comprises a finger substrate made, e.g., from a suitable flexible non-conductive material such as silicone or other implantable lead materials, as is known in the art." (Column 5, lines 1-4).
7. In regard to claims 3, 18, and 34, Kuzma discloses, "...the electrode array is made in the form of a silicone paddle..." (Column 3, lines 30-31).
8. In regard to claims 5 and 20, Kuzma discloses, "The flexible substrate normally assumes a planar flat shape..." (Column 2, lines10-11).

9. In regard to claims 8 and 22 and 36, Kuzma discloses a medical lead covered in an insulative membrane. The outer surface of the membrane has electrode contacts, while the inner surface of the membrane is in contact with the "shape-memory element" (12) (See figure 1b).

10. In regard to claim 9 and 23 and 37, Kuzma discloses an insulative membrane enclosing the "shape-memory element" (12). The electrode is also associated with the inner surface of the insulative membrane because "the electrical wires (15) that are electrically connected to the electrode contacts (11) are wound around the shape-memory element" (Column 3, lines 41-43; Also see figure 1b).

11. In regard to claims 10, 26, and 38, Kuzma discloses, "In accordance with yet another aspect of the invention, the electrode array includes a membrane as an integral part thereof that prevents ingrowth of tissue inside the electrode array, thereby facilitating repositioning, removal, and/or reinsertion of the electrode array as required." (Column 1, lines 60-67; Column 2 lines 1-2).

12. In regard to claims 11, 27, and 39, Kuzma discloses, "A paddle-type electrode or electrode array is implantable like a percutaneously inserted lead, i.e., without requiring major surgery, but once inserted, expands to provide a platform for many electrode configurations". (Abstract, lines 1-4).

13. In regard to claims 12, 28, and 40, Kuzma discloses, "In order to implant the electrode array, the needle (30) with electrode array (10) and insertion

tool (20) inside, is inserted into the spinal cord cavity" (Column 4, lines 44-45). It is well known in the art that the "spinal cord cavity" is the epidural space as is seen in US Applications such as 10/691859 and10/131980 and US Patent 6,754,539, among others.

14. In regard to claims 13, 29, and 41, Kuzma discloses, "In order to implant the electrode array, the hollow tube or needle (with the folded or compressed electrode array therein) is injected into the living tissue of the desired implant site. The folded electrode array is then expelled from the hollow tube and allowed to assume its expanded or unfolded state within the tissue" (Column 2, lines 18-22).

15. In regard to claims 14, 15, 30, 31, 42, and 43, Kuzma discloses, "In a preferred embodiment, such electrodes (11) comprise deployable, paddle-type, multicontact electrodes useful for spinal stimulation" (Column 1, lines 9-11).

16. In regard to claim 16, in figure 1, Kuzma discloses a shape memory element (12) associated with an insulative membrane, which extends along the longitudinal axis and has a plurality of secondary segments (edge portions 16) that branch off the main segment, with at least one electrode associated with the insulative membrane. As previously discussed, Kuzma discloses, "...the electrode array (10), is made in the form of a silicone paddle, having a number of electrode contacts..." (Column 3, lines 30-33)

17. In regard to claim 24, figure 1 depicts a medical lead that has secondary segments, which branch bilaterally from the main segment.

18. In regard to claim 32, Kuzma discloses, "The flexible substrate normally assumes a planar flat shape..." (Column 2, lines 10-11). Kuzma further discloses, "...the electrode array (10) is made in the form of a silicone paddle having a number of electrode contacts (11)..." (Column 3, lines 30-32).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

19. Claims 4, 19, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma et al. in view of Gerber et al. (US 2001/0025192 A1). Kuzma is discussed above. Gerber teaches, "The lead body (115) is formed of a non-conductive, body compatible, flexible, outer tubular sheath (260)...." (Paragraph 54, lines 3-6; Figures 8 and 9). The invention disclosed in this application is "...an implantable medical lead having at least one stimulation electrode wherein the lead is implanted near sacral nerves for stimulation of a bundle of sacral nerve fibers." (Paragraph 3, lines 3-6). Furthermore, Gerber discloses, "The distal electrode array

segment (160) can be percutaneously introduced..." (Paragraph 59, lines 5-7). Gerber also discloses, "But too close or tight a contact of the electrode with the sacral nerve can also cause inflammation or injury to the nerve diminishing efficacy and possibly causing patient discomfort (Paragraph 14, lines 16-29). Furthermore, Gerber discloses, "...the lead can allow for some movement of the lead without deteriorating the capture of the sacral nerves. Because the electrode does not need to be in direct contact with the nerve fibers and due to the large electrode area, a small amount of movement from the original implant position does not reduce the nerve capture (Paragraph 24, lines 3-8). In view of these teachings, it would be obvious to one skilled in the art to modify the Kuzma medical lead to have a tubular insulative membrane in order to prevent patient discomfort and injury to the nerves being stimulated.

20. Claims 6 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma in view of Cross et al. (US 2003/0204228). Cross teaches, "In another embodiment, the paddle is curved about a vertical axis to substantially match the shape of a human spinal cord dura mater to help reduce lead migration." (Abstract, lines 9-12) (Also see paragraph 29, lines (1-4). In view of this teaching, it would be obvious to one of ordinary skill in the art to modify the Kuzma medical lead in order to match the shape of the human spinal cord dura mater and thereby reduce lead migration.

21. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuzma in view of Boling et al. (US 6,597,953). Kuzma is discussed above. Boling teaches "A furcated medical electrical lead for neurological applications...having a plurality of distal end segments, each of which bears at least one distal electrode for electrographic sensing or electrical stimulation" (Abstract, lines 2-4). In figure 8, Boling discloses a medical lead, which has unilateral branching. Since this lead is used for neurological stimulation, just as the lead disclosed by Kuzma, it would have been obvious to one skilled in the art to modify Kuzma with the teachings of Boling.

Allowable Subject Matter

22. Claims 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joy P. Patel whose telephone number is 571-272-5556. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)-272-6996. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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